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August 21, 1997

Dr. C. W. Jameson
National Toxicology Program
Report on Carcinogens
MD WC-05
P. O. Box 12233
Research Triangle, NC 27709

Dear Dr. Jameson:

I am writing in response to the invitation for public comments regarding your upcoming review of saccharin announced in the Federal Register on July 11, 1997. As a scientist and technical advisor to Cumberland Packing Corp., I am familiar with the scientific data base on saccharin and I firmly believe that saccharin is not a carcinogen, certainly not a human carcinogen. My conclusion is based on the extensive scientific evidence including mechanistic studies and epidemiological evidence. The human use record of saccharin is unique among food additives as it has been in use by humans for almost 100 years. All of the epidemiological studies clearly indicate a lack of association between saccharin ingestion and increase in the incidence of bladder cancer in humans.

The case against saccharin centered around the finding that rats fed high doses of sodium saccharin develop higher incidence of bladder cancer than control rats. However, when saccharin acid is administered, there is no increase in bladder tumors incidence. Recent studies indicate that this increase in the incidence of bladder tumors occurs in rats fed other sodium salts of organic acids including ascorbic acid. Studies conducted with other animal species, including mice, hamsters and monkeys, show no association between sodium saccharin ingestion and the incidence of bladder tumors. Recently, the results of a study involving monkeys maintained on sodium saccharin show that these animals did not experience any increase in the incidence of bladder tumors. These results are highly significant. I believe, as many scientists do that the monkey is a more appropriate species model than rats when extrapolating animal data to humans. Dr. Cohen and coworkers at the University of Nebraska developed a comprehensive mechanistic explanation for sodium saccharin's action in rats and why these findings are not relevant to humans and other animal species.

I believe that the epidemiological data and the animal studies including the mechanistic studies provide strong and highly convincing evidence that this phenomenon is specific to sodium saccharin and is not relevant to humans and does not seem to occur in other saccharin forms.

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I am sure that the distinguished panel of scientists who will be reviewing the data on saccharin will agree that it is highly important to send clear messages to the public regarding the scientific evidence. It is very confusing to consumers when they learn that prestigious organizations, such as the Joint Expert Committee on Food Additives of the World Health Organization, the Scientific Committee on Foods of the European Community, Diabetic Associations and Dietetic Associations support the continued availability of saccharin on the one hand and that saccharin is listed as "anticipated" carcinogen on the other hand.

We support your efforts to review the safety of this sweetener and we urge you to delist saccharin from the NTP list of "anticipated" carcinogens. This action, I believe, will go a long way assuring the public that scientific conclusions reached by scientific bodies are based solely on the scientific evidence.

Sincerely,



Abraham I. Bakal, Ph.D.
President

AIB/bf